PMA Monthly approvals from 5/1/2016 to 5/31/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160002	05/18/2016	PMAO - PMA Origi	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the PD-L1(SP142) Assay. The device is indicated for the following: VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplifcation Kit on a VENTANA BenchMark ULTRA instrument. PD-L1 status is determined by the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity. PD-L1 expression in >= 5% IC determined by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma tissue is associated with increased objective response rate (ORR) in a non-randomized study of TECENTRIQ (atezolizumab).

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S186	05/03/2016	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for an alternate capacitor to be used in the communications module.
P830055/S168	05/03/2016	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for changes to the Attune surgical technique (additional cautionary statements, new instruments, instrument modification, and typographical/editorial changes).
P850064/S031	05/24/2016	R - Real-Time Proc	MODEL 204 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for changing the screw material in the Patient Box model 314 of the Life Pulse High Frequency Ventilator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880086/S261	05/12/2016	N - Normal 180 Day	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for updates to the Merlin@home EX2000 v8.2 Software and the Merlin.net MN5000 v7.4 Software.
P890003/S345	05/03/2016	N - Normal 180 Day	MEDTRONIC MODEL 31301 CARELINK EXPRESS APP.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Model 31301 CareLink Express App.
P890003/S352	05/24/2016	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for changes to the application software and associated labeling for ICD and CRT-D devices
P900033/S053	05/09/2016	N - Normal 180 Day	INTEGRA(R) DERMAL REGENERATION TEMPLATE, INTEGRA(R) MESHED DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Approval of two new product sizes (i.e., 4cm x 4cm and 7cm x 7cm) and revised packaging that permits inclusion of a stapler and staples in the Integra Omnigraft Dermal Regeneration Matrix kit. The device, as modified, will be marketed under the trade name Omnigraft Dermal Regeneration Matrix.
P900033/S054	05/03/2016	O - Normal 180 Day	INTEGRA DERMAL REGENERATION TEMPLATE - TERMINALLY STERILIZED	INTEGRA LIFESCIENCES CORP.	Approval for a manufacturing site located at Integra LifeSciences Corporation, 109 Morgan Lane, Plainsboro, New Jersey, as a new and alternate manufacturing facility.
P910023/S362	05/12/2016	N - Normal 180 Day	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/II/+, FAMILY OF ICDS	St. Jude Medical	Approval for updates to the Merlin@home EX2000 v8.2 Software and the Merlin.net MN5000 v7.4 Software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910023/S362	05/12/2016	N - Normal 180 Day	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/II/+, FAMILY OF ICDS	ST. JUDE MEDICAL, INC.	Approval for updates to the Merlin@home EX2000 v8.2 Software and the Merlin.net MN5000 v7.4 Software.
P930029/S052	05/11/2016	O - Normal 180 Day	RF MARINR CATHETERS, RF ENHANCER II CATHETERS, RF CONTRACTR CATHETERS AND RF CONDUCTR CATHETERS	MEDTRONIC INC.	Approval for a manufacturing site located at Steris Isomedix, 2500 Commerce Drive, Libertyville, Illinois, as a contract sterilizer.
P950029/S108	05/11/2016	Y - 135 Review Tra	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR	SORIN GROUP- CRM	Approval for updates to the coating dispensing and curing manufacturing processes for the microelectronic assemblies.
P950037/S161	05/02/2016	N - Normal 180 Day	SETROX S 53, SAFIO S 53	BIOTRONIK, INC.	Approval for full body scanning of the ProMRI CRT-D System.
P950037/S162	05/27/2016	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for programmer software PSW 1506.U/1.
P960040/S365	05/03/2016	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for an alternate capacitor to be used in the communications module.
P980016/S562	05/03/2016	N - Normal 180 Day	EVERA MRI ICD, S DR ICD, S VR ICD, XT DR ICD, ST VR ICF, INTRINSIC 30 ICD, MARQUIS VR ICD, MAXIMO II ICD, PROTECT ICD, S	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for the Model 31301 CareLink Express App.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S582	05/24/2016	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for changes to the application software and associated labeling for ICD and CRT-D devices.
P980018/S021	05/27/2016	R - Real-Time Proc	DAKO HERCEPTEST	DAKO A/S	Approval for addition of Dako PT Link programmable water bath, PT200 for pre-treatment of tissue sections when using HercepTest for Automated Link Platforms.
P980023/S074	05/02/2016	N - Normal 180 Day	Drug-Eluting Permanent Defibrillator Electrodes, Accessories to Implantable Pacemaker Pulse Generator	BIOTRONIK, INC.	Approval for full body scanning of the ProMRI CRT-D System.
P980035/S447	05/03/2016	N - Normal 180 Day	ADAPTA, VERSA, SENSIA IPG. ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ENOUKSE E2 IOG, KAPPA D IPG,KAPPA DR IP	MEDTRONIC INC.	Approval for the Model 31301 CareLink Express App.
P980049/S114	05/11/2016	Y - 135 Review Tra	PARADYM VR 8750,PARADYM DR 8750,PARADYM RF VR 9750,PARADYM RF DR 9750 (ZL101),PARADYM RF VR 9750, PARADYM RF DR 9750(ZL10	SORIN GROUP- CRM	Approval for updates to the coating dispensing and curing manufacturing processes for the microelectronic assemblies.
P990004/S025	05/16/2016	N - Normal 180 Day	SURGIFLO HEMOSTATIC MATRIX KIT WITH THROMBIN	ETHICON, INC.	Approval for a packaging change to introduce a new packaging configuration for the Thrombin Kit Package for SURGIFLO Hemostatic Matrix Kit with Thrombin. This change was requested for the manufacturing site located at SteriPack Medical Poland SP. ZO.O., Poland, for the contract packaging of the SURGIFLO Hemostatic Matrix Device and the sterilizing site located at Synergy Health Ede BV, Netherlands, for the sterilization of the SURGIFLO Hemostatic Matrix Device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000008/S035	05/23/2016	O - Normal 180 Day	LAP-BAND ADJUSTABLE GASTIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	approval for a manufacturing site located at Apollo Endosurgery, Building 13.3, Zona Franca Coyol, Alajuela, Costa Rica
P000009/S065	05/02/2016	N - Normal 180 Day	PROGRAMMER SOFTWARE (1507.U) FOR THE ICS 3000/RENAMIC PROGRAMMERS	BIOTRONIK, INC.	Approval for full body scanning of the ProMRI CRT-D System.
P000009/S066	05/27/2016	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for programmer software PSW 1506.U/1.
P000025/S086	05/11/2016	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the optional protection covering accessory called the WaterWear for SONNET or OPUS 2 behind-the-ear (BTE) audio processors.
P000025/S087	05/24/2016	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the SONNET Rechargeable Battery Kit and the SONNET Mini Battery Pack cable and adapter.
P010012/S411	05/03/2016	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for an alternate capacitor to be used in the communications module.
P010015/S287	05/03/2016	N - Normal 180 Day	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for the Model 31301 CareLink Express App.
P010023/S012	05/03/2016	O - Normal 180 Day	MAXUM SYSTEM	OTOTRONIX, LLC	Approval for a manufacturing site located at Ototronix LLC, 5000 Township Parkway, St. Paul, Minnesota to perform manufacturing and distribution.
P010031/S523	05/03/2016	N - Normal 180 Day	BRAVA CRT-D, BRAVA QUAD CRT-D, CONCERTO ICD, CONCERTO II CRT-D, CONSULTA CRT-D; MAXIMO II CRT-D, PROTECTA CRT-D, PROTECT	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Model 31301 CareLink Express App.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S542	05/24/2016	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for changes to the application software and associated labeling for ICD and CRT-D devices.
P020014/S044	05/12/2016	O - Normal 180 Day	ESSURE SYSTEM	BAYER PHARMA AG	Approval of changes to the post-approval study protocol.
P030005/S133	05/03/2016	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for an alternate capacitor to be used in the communications module.
P030035/S139	05/12/2016	N - Normal 180 Day	ANTHEM, ALLURE/RF, QUADRA ALLURE/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for updates to the Merlin@home EX2000 v8.2 Software and the Merlin.net MN5000 v7.4 Software.
P030054/S292	05/12/2016	N - Normal 180 Day	PROMOTE/+/RF/ Q,PROMOTE ACCEL,PROMOTE QUADRA,UNIFY,UNIFY ASSURA,UNIFY QUADRA,QUADRA ASSURA,EPIC+/HF/HF+/ IIHF/II+HF,ATLAS+	St. Jude Medical	Approval for updates to the Merlin@home EX2000 v8.2 Software and the Merlin.net MN5000 v7.4 Software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030054/S292	05/12/2016	N - Normal 180 Day	PROMOTE/+/RF/ Q,PROMOTE ACCEL,PROMOTE QUADRA,UNIFY,UNIFY ASSURA,UNIFY QUADRA,QUADRA ASSURA,EPIC+/HF/HF+/ IIHF/II+HF,ATLAS+	ST. JUDE MEDICAL, INC.	Approval for updates to the Merlin@home EX2000 v8.2 Software and the Merlin.net MN5000 v7.4 Software.
P040029/S003	05/26/2016	O - Normal 180 Day	EUCLID SYSTEMS ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATIO N	Approval of name change from JSZ Orthokeratology (oprifilconA) Contact Lenses for Overnight Wear to Euclid System Orthokeratology (oprifilcon A) Contact Lenses for Overnight Wear.
P050023/S094	05/02/2016	N - Normal 180 Day	IPERIA 7 HF-T (DR-1) & (DF-4); INVENTRA 7 HF-T (DF-1) & (DF-4)	BIOTRONIK, INC.	Approval for full body scanning of the ProMRI CRT-D System.
P050023/S097	05/27/2016	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for programmer software PSW 1506.U/1.
P050037/S065	05/31/2016	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the following three changes: 1) Qualification testing of the BI spore strips, 2) Bioburden test frequency, and 3) Endotoxin detection limit.
P050052/S073	05/02/2016	Y - 135 Review Tra	RADIESSE (+) 0.8CC, RADIESSE (+) 1.5CC	MERZ NORTH AMERICA, INC	Approval for using an alternate supplier for the syringe barrels and assembly of the syringe components.
P050052/S076	05/31/2016	Y - 135 Review Tra	RADIESSE LOW VISCOSITY INJECTABLE IMPLANT; RADIESSE (+) LIDOCAINE DERMANL FILTER	MERZ NORTH AMERICA, INC	Approval for the following three changes: 1) Qualification testing of the BI spore strips, 2) Bioburden test frequency, and 3) Endotoxin detection limit.
P060002/S036	05/16/2016	Y - 135 Review Tra	FLAIR ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR	Approval of a new polytetrafluoroethylene (PTFE) resin.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060027/S080	05/11/2016	Y - 135 Review Tra	PARADYM CRT-D 8750,PARADYM RF CRT-D 9750(ZL101),PARADYM RF CRT-D 9750 (ZL102),INTENSIA CRT-D	SORIN GROUP- CRM	Approval for updates to the coating dispensing and curing manufacturing processes for the microelectronic assemblies.
P060040/S056	05/24/2016	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for a software upgrade to the Mobile Power Unit (MPU).
P060040/S057	05/24/2016	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for revisions to the Pocket Controller Primary Application software and the Liquid Crystal Display (LCD) Application software.
P070008/S070	05/02/2016	N - Normal 180 Day	COROX OTW 75 BP & 85 BP; COROX OTW-L 75 BP & 85 BP; COROX OTW-S 75 BP & 85 BP	BIOTRONIK, INC.	Approval for full body scanning of the ProMRI CRT-D System.
P070008/S072	05/27/2016	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for programmer software PSW 1506.U/1.
P070009/S016	05/16/2016	O - Normal 180 Day	Ethicon Endo-Surgery Curved Adjustable Gastric Band with Sutureless Port and Applier; Ethicon Endo-Surgery Gastric Band Sutureless Port and Applier	OBTECH MEDICAL GMBH	Approval for the trade name changes from REALIZE Adjustable Gastric Band-C with Injection Port and Applier to Ethicon Endo-Surgery Curved Adjustable Gastric Band with Sutureless Port and Applier, and REALIZE Injection Port and Applier to Ethicon Endo-Surgery Gastric Band Sutureless Port and Applier.
P070014/S037	05/31/2016	P - Panel Track	BARD LIFESTENT VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval for the Bard® LifeStent® Vascular Stent System. The Bard® LifeStent® Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and popliteal artery with reference vessel diameters ranging from 4.0 to 6.5 mm.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070026/S031	05/04/2016	O - Normal 180 Day	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for a manufacturing site located at Orchid Orthopedics Solutions, 4600 East Shelby Drive, Suite 1, Memphis, Tennessee, 38118.
P080012/S033	05/26/2016	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for the addition of an alternate custom integrated circuit or also called an application specific circuit (ASIC).
P080030/S017	05/13/2016	O - Normal 180 Day	GLAUKOS ISTENT TRABECULAR MICRO-BYPASS STENT SYSTEM	GLAUKOS, CORPORATION	Approval for protocol modifications for the PAS2 study.
P090013/S209	05/03/2016	N - Normal 180 Day	RENO MRI SURESCAN IPG	MEDTRONIC INC.	Approval for the Model 31301 CareLink Express App.
P090016/S013	05/24/2016	Y - 135 Review Tra	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Sharing equipment used during the manufacture of belotero balace dermal filler across other product lines.
P100003/S006	05/17/2016	R - Real-Time Proc	SECURE -C CERVICAL ARTIFICIAL DISC	GLOBUS MEDICAL INC.	Approval for clarifying the worst-case temperature rise for the subject device and revising the labeling to adequately reflect those temperature. The Secure-C Cervical Artificial Disc can be now be labeled as MR Compatible.
P100009/S015	05/10/2016	N - Normal 180 Day	MITRACLIP NT CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval for a material change to the gripper, design and manufacturing changes to the delivery system, and changes to device packaging.
P100010/S054	05/17/2016	R - Real-Time Proc	Arctic Front Advance Cardiac CryoAblation Catheters	MEDTRONIC CRYOCATH LP	Approval for modifications to the catheter blood sensor board for the Arctic Front Advance catheters (models 2AF234 & 2AF284).
P100045/S008	05/02/2016	O - Normal 180 Day	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	St. Jude Medical	Approval for an alternate contract sterilizer site located at St Jude Medical-Sylmar, 15900 Valley View Court, Sylmar, California, 93342, to perform as an alternate ethylene oxide sterilization vendor for the CardioMEMS PA Sensor and Delivery Catheter.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110005/S001	05/23/2016	R - Real-Time Proc	Gel-Syn¿	IBSA INSTITUT BIOCHIMIQUE SA	Approval for the addition of a needle to the Gel-Syn packaging configuration
P110033/S018	05/31/2016	P - Panel Track	JUVEDERM VOLBELLA XC	ALLERGAN	Approval for JUVÉDERM VOLBELLA® XC injectable gel. The device is indicated for injection into the lips for lip augmentation and for correction of perioral rhytids in adults over the age of 21.
P110037/S023	05/20/2016	N - Normal 180 Day	COBAS AMPLIPREP/COBAS TAQMAN CYTOMEGALOVIRUS TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for use with hematopoietic stem-cell transplant patients and to increase the whole blood stability claim in the Package Insert.
P120002/S007	05/09/2016	O - Normal 180 Day	CORDIS S.M.A.R.T.AND S.M.A.R.T.CONTROL VASCULAR STENT SYSTEM	CORDIS CORP.	Approval for updated labeling to include the post-approval study results.
P120006/S023	05/05/2016	R - Real-Time Proc	OVATION ABDOMINAL STENT GRAFT SYSTEM	TRIVASCULAR INC	Approval for a change in bottom material for the inner and outer pouch for the AutoInjector.
P120023/S001	05/12/2016	O - Normal 180 Day	KAMRA INLAY	ACUFOCUS, INC.	Approval of the post approval study protocol.
P130009/S058	05/23/2016	S - Special CBE	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a new in-process inspection for device accessories.
P130013/S008	05/03/2016	O - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE DEVICE	BOSTON SCIENTIFIC CORP.	Approval of the BSC Ireland facility.
P130024/S012	05/05/2016	S - Special CBE	LUTONIX DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval for minor changes to the Indications for Use statement and Instructions for Use document.
P130028/S005	05/26/2016	R - Real-Time Proc	ALGOVITA SPINAL CORD STIMULATION SYSTEM	ALGOSTIM, LLC	Approval for design changes to the Model 4500 Clinician Programmer.
P130029/S001	05/16/2016	Y - 135 Review Tra	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Approval of a new polytetrafluoroethylene (PTFE) resin.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140008/S003	05/23/2016	O - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	approval for a manufacturing site located at Apollo Endosurgery, Building 13.3, Zona Franca Coyol, Alajuela, Costa Rica
P140010/S017	05/05/2016	S - Special CBE	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for minor changes to the Indications for Use statement and Instructions for Use document.
P140011/S001	05/12/2016	N - Normal 180 Day	MAMMOMAT INSPIRATION WITH TOMOSYNTHESIS OPTION	SIEMENS MEDICAL SOLUTIONS USA, INC.	Approval for change to the indications for use statement. The device, as modified, will be marketed under the trade name MAMMOMAT Inspiration with Tomosynthesis Option and is indicated for acquisition of 2D as well as 3D digital mammography images to be used in screening and diagnosis of breast cancer. A screening examination may consist of a 3D DBT image set and/or a 2D FFDM image set.
P140028/S010	05/11/2016	O - Normal 180 Day	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Approval of the Boston Scientific Maple Grove site as a stent component manufacturing site for the Innova stent.
P140031/S016	05/23/2016	S - Special CBE	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a new in-process inspection for device accessories.
P150003/S011	05/31/2016	O - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Approve Galway, Ireland as a stent manufacturing site for synergy.
P150004/S001	05/26/2016	O - Normal 180 Day	Axium Neurostimulator System	SPINAL MODULATION, INC	Approval of the post-approval study protocol.

Total: 76

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S081	05/06/2016	X - 30-Day Notice	VISTAKON (etafilcon A) Brand Contact Lenses	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Modification to the statistical method and procedures for product sampling of finished product release.
N970003/S188	05/25/2016	X - 30-Day Notice	ADVANTIO, INGENIO, VITALIO, ESSENTIO, PROPONENT, ACCOLADE, ALTRUA 2	BOSTON SCIENTIFIC CORP.	Additional leak tester to the battery manufacturing line.
N970003/S189	05/25/2016	X - 30-Day Notice	INGENIO 2 PACEMAKERS. ALTRUA 2 , ESSENTIO, PROPONENT, ACCOLADE. IMPLANTABLE PULSE GENERATOR (PG), ADVANTIO, INGENIO, VITALIO, FORMIO	BOSTON SCIENTIFIC CORP.	Addition of a new acrylic dispense system in the pulse generator header manufacturing process.
N970012/S115	05/31/2016	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESES (IPP)	BOSTON SCIENTIFIC CORP.	Modifications to the injection mold for the Quick Connect Collet.
P790007/S048	05/31/2016	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE VALVED CONDUIT	MEDTRONIC HEART VALVES	Addition of three new tissue suppliers.
P840001/S326	05/05/2016	X - 30-Day Notice	RESTORE, ITREL. AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS.	MEDTRONIC NEUROMODULATION	Relocation of the parts cleaning of the impacted piece parts (components) from the Medtronic Sullivan Lake (SL) facility to the Medtronic Rice Creek (RC) facility.
P840001/S327	05/27/2016	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Updated software inspection in the distribution center facility to test the batteries of implantable neurostimulators returned from the field prior to restocking.
P840064/S061	05/18/2016	X - 30-Day Notice	VISCOAT OPHTHALMIC VISCOSURGICAL DEVICES; DUOVISC OPTHALMIC VISCOSURGICAL DEVICES; DISCOVISC OPTHALMIC VISCOSURGICAL DEVICE	ALCON LABORATORIES	Implementation of changes made to the depyrogenation process for the ophthalmic viscoelastic devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860003/S086	05/05/2016	X - 30-Day Notice	THERAKOS UVAR XTS Photopheresis System Procedural Kit	THERAKOS, INC.	Manufacturing process change to the exterior printing of the Tyvek lid stock for the Therakos UVAR XTS Procedural Kit used with the Therakos UVAR XTS Photopheresis System.
P860004/S248	05/05/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Relocation of the parts cleaning of the impacted piece parts (components) from the Medtronic Sullivan Lake (SL) facility to the Medtronic Rice Creek (RC) facility.
P860004/S249	05/13/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Manufacturing tool change- Medtronic uses a third party vendor to manufacture sub-assembly components. The vendor would like to use a new arbor press which has press force monitoring capabilities, opposed to the current arbor press which does not have such capabilities. The force monitoring will be an internal process, and no device specifications are changed.
P860057/S146	05/06/2016	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Additional bovine pericardial tissue supplier.
P870078/S032	05/31/2016	X - 30-Day Notice	HANCOCK LOW POROSITY VALVED CONDUIT	MEDTRONIC INC.	Addition of three new tissue suppliers.
P890047/S047	05/18/2016	X - 30-Day Notice	PROVISC OPHTHALMIC VISCOSURGICAL DEVICE	ALCON RESEARCH, LTD.	Implementation of changes made to the depyrogenation process for the ophthalmic viscoelastic devices.
P890055/S062	05/27/2016	X - 30-Day Notice	CODMAN 3000 SERIES IMPLANTABLE INFUSION PUMP.	CODMAN	Change for a new packaging equipment to seal the pouches for the Codman 3000 Constant-Flow Implantable Infusion Pump O.R. Prep Kit Tubing Assembly. External supplier, Command Medical Products (Command), has requested implementation of new packaging sealing equipment, a Sencorp bar sealer (12-PL/2) with a removable work surface. The supplier has requested the change as a process improvement.
P900056/S153	05/25/2016	X - 30-Day Notice	Rotablator Rotational Atherectomy System (ROTAWIRE GUIDEWIRE WITH WIRECLIP TORQUER)	BOSTON SCIENTIFIC CORP.	Change to the wireClip Torquer sub-assembly process.
P910056/S022	05/27/2016	X - 30-Day Notice	ENVISTA HYDROPHOBIC INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Addition of an alternate dose audit study facility for the en Vista® Hydrophobic Acrylic Intraocular Lens (IOL).
P930038/S081	05/06/2016	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	ST. JUDE MEDICAL, INC.	Move the Carrier Tube component manufacturing to the existing Puerto Rico facility and automate the Carrier Tube manufacturing process.
P930038/S082	05/12/2016	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICE	ST. JUDE MEDICAL, INC.	Revised inspection requirements for the insertion sheath and carrier tube components of the Angio-Seal Vascular Closure device.
P940035/S012	05/06/2016	X - 30-Day Notice	ALERE NMP22(TM) TEST	ALERE SCARBOROUGH, INC	Change in the manufacturing process of the Alere NMP22 Test, in which the manufacture of the antigens used in the manufacture of the urine calibrators and urine controls has been outsourced to a Third Party Vendor.
P950022/S092	05/01/2016	X - 30-Day Notice	Durata and Optisure HV leads	ST. JUDE MEDICAL, INC.	Alternate analytical testing laboratory and implementation of an identity test for monolithic controlled release devices.

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P960009/S249	05/05/2016	X - 30-Day Notice	ACTIVA DEEP BRIAN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Relocation of the parts cleaning of the impacted piece parts (components) from the Medtronic Sullivan Lake (SL) facility to the Medtronic Rice Creek (RC) facility.
P960009/S250	05/27/2016	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Updated software inspection in the distribution center facility to test the batteries of implantable neurostimulators returned from the field prior to restocking.
P960013/S081	05/01/2016	X - 30-Day Notice	Tendril SDX, ST, STS and OptiSense LV leads	PACESETTER, INC.	Alternate analytical testing laboratory and implementation of an identity test for monolithic controlled release devices.
P960016/S065	05/19/2016	X - 30-Day Notice	LIVEWIRE(R) TC CARDIAC ABLATION SYSTEM	St. Jude Medical	Acceptance of modified manufacturing criteria and removal of in-process inspection step for the anchor sleeve assembly component.
P960030/S044	05/01/2016	X - 30-Day Notice	IsoFlex Optim LV leads	PACESETTER, INC.	Alternate analytical testing laboratory and implementation of an identity test for monolithic controlled release devices.
P960040/S369	05/09/2016	X - 30-Day Notice	Origen, Dynagen, Inogen EL ICD; Origen, Dynagen, Inogen MINI ICD	BOSTON SCIENTIFIC	Automation of transformer component movement at final electrical test and redesign of the associated system fixtures at the supplier.
P960040/S371	05/17/2016	X - 30-Day Notice	NG3 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) ORIGEN EL ICD: D050, D051, D052, D053 INOGEN EL ICD: D140, D141, D142, D143 DYNAGEN EL ICD: D150, D151, D152, D153 NG2.5 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) ORIGEN MINI ICD: D000, D001, D002, D003 INOGEN MINI ICD D010, D011, D012, D013 DYNAGEN MINI ICD: D020, D021, D022, D023.	BOSTON SCIENTIFIC	Implementation of an automated optical inspection of components on device printed circuit boards.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S372	05/25/2016	X - 30-Day Notice	NG3 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(ICD). ORIGEN , INOGEN, DYNAGEN EL ICD'S. NG2.5 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR . ORIGEN, INOGEN DYNAGEN MINI ICD'S	BOSTON SCIENTIFIC	Addition of a new acrylic dispense system in the pulse generator header manufacturing process.
P960043/S092	05/28/2016	X - 30-Day Notice	PROSTAR XL 10F PERCUTANEOUS VASCULAR SURGICAL SYSTEM	ABBOTT VASCULAR INC.	Modification to the needle retention force specification.
P970004/S212	05/05/2016	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Relocation of the parts cleaning of the impacted piece parts (components) from the Medtronic Sullivan Lake (SL) facility to the Medtronic Rice Creek (RC) facility.
P970031/S052	05/31/2016	X - 30-Day Notice	FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC HEART VALVES	Addition of three new tissue suppliers.
P980016/S584	05/09/2016	X - 30-Day Notice	EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT CR ICD, EVERA XT VR ICD, MAXIMO II ICD, PROTECTA ICD, PROTECTA XT ICD, SECURA ICD, VIRTUOSO II DR/VR ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the integrated circuit wafer manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S588	05/25/2016	X - 30-Day Notice	Evera MRI ICD DDMB1D4, DDMC3D4, DVMB1D4, DVMC3D4; Evera S DR ICD DDBC3D1, DDBC3D4; Evera S VR ICD DVBC3D1, DVBC3D4; Evera XT DR ICD DDBB1D1, DDBB1D4; Evera XT VR ICD DVBB1D1, DVBB1D4; Visia AF MRI VR ICD DVFB1D4, DVFC3D4; Visia AF VR ICD DVAB1D1, DVAB1D4, DVAC3D1, DVAC3D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the supplier's cleaning process for the accelerometer.
P980016/S589	05/25/2016	X - 30-Day Notice	EVERA MRI, S DR ,S VR, XT DR , XT VR ICD'S; MAXIMO II ICD; PROTECTA ICD, PROTECTA XT ICD; SECURA ICD; VIRTUOSO II DR/VR ICD; VISIA AF MRI VR ICD; VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the wafer manufacturing process.
P980035/S462	05/09/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG,RELIA IPG.	MEDTRONIC INC.	Changes to the integrated circuit wafer manufacturing process.
P980035/S463	05/23/2016	X - 30-Day Notice	Adapta, Versa, Sensia IPG ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1, SEDR01, SESR01, VEDR01, ADD01, SEDRL1, SED01, SES01, ADSR01, ADSR03, ADSR06, ADVDD01; Relia IPG RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	Alternate printed wiring board for use in hybrid manufacturing.
P980040/S068	05/13/2016	X - 30-Day Notice	TECNIS 1-PIECE IOL, MULTIFOCAL 1-PIECE IOL, TORIC 1-PIECE IOL WITH THE TECNIS iTEC PRELOADED DELIVERY SYSTEM	ABBOTT MEDICAL OPTICS INC	Addition of an alternate molding supplier for the lower and upper body components used in all TECNIS iTec Preloaded Delivery System lens models manufactured at the AMO Puerto Rico and AMO Groningen BV sites.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980043/S054	05/31/2016	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Addition of three new tissue suppliers.
P980044/S032	05/13/2016	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Modifications to existing cleanrooms in the SUPARTZ FX manufacturing facility.
P990023/S014	05/18/2016	X - 30-Day Notice	CELLUGEL(R) OPHTHALMIC VISCOSURGICAL DEVICE (OVD)	ALCON LABORATORIES	Implementation of changes made to the depyrogenation process for the ophthalmic viscoelastic devices.
P990064/S063	05/31/2016	X - 30-Day Notice	MOSAIC PORCINE BIOPROSTHETIC	MEDTRONIC HEART VALVES	Addition of three new tissue suppliers.
P000012/S055	05/13/2016	X - 30-Day Notice	COBAS AMPLICOR (TM) HEPATITIS C VIRUS (HCV) TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new filler system and transfer of the microtube filling operations of controls to a new laboratory.
P000037/S045	05/31/2016	X - 30-Day Notice	ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGIES, INC.	the addition of a new piece of test equipment used in the manufacture of heart valve subassemblies
P000039/S055	05/04/2016	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	AGA MEDICAL CORP.	Addition of a new laser welding system.
P000053/S063	05/31/2016	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM (AUS)	BOSTON SCIENTIFIC CORP.	Modifications to the injection mold for the Quick Connect Collet.
P010003/S022	05/04/2016	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Change to the frequency of the bioburden assessments from quarterly to annually for BioGlue Accessories that undergo Ethylene Oxide (EO) sterilization, a modification to the Limulus Amebocyte Lysate (LAL) test method for BioGlue to include agitation during the extraction process and change the dilution to test the BioGlue extract, and to eliminate the quarterly autoclave cycle verification and the quarterly issuance of Certificates of Completion for the autoclaves used in production and microbiology.
P010012/S415	05/09/2016	X - 30-Day Notice	Dynagen, Inogen, Origen CRT-D; Dynagen, Inogen, Origen X4 CRT-D	BOSTON SCIENTIFIC CORP.	Automation of transformer component movement at final electrical test and redesign of the associated system fixtures at the supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S418	05/17/2016	X - 30-Day Notice	NG3 CARDIAC RESYNCHRONIZATION THERAPY-DEFIBRILLATOR (CRT-D) DYNAGEN CRT-D: G150, G151, G154, X4 CRT-D; G156, G158 INOGEN CRT-D: G140, G141, X4 CRT-D: G146, G148 ORIGEN CRT-D; G050, G051, X4 CRT-D: G056, G058.	BOSTON SCIENTIFIC CORP.	Implementation of an automated optical inspection of components on device printed circuit boards.
P010012/S419	05/25/2016	X - 30-Day Notice	NG3 CARDIAC RESYNCHRONIZATION THERAPY-DEFIBRILLATOR (CRT-D). DYNAGEN CRT-D, X4 CRT-D; INOGEN CRT-D, X4 CRT-D; ORIGEN CRT-D, X4 CRT-D	BOSTON SCIENTIFIC CORP.	Addition of a new acrylic dispense system in the pulse generator header manufacturing process.
P010015/S299	05/09/2016	X - 30-Day Notice	CONSULTA, SYNCRA, VIVA CRT-P	MEDTRONIC INC.	Changes to the integrated circuit wafer manufacturing process.
P010015/S300	05/24/2016	X - 30-Day Notice	Consulta CRT-P C4TR01; Syncra CRT-P C2TR01; Viva CRT-P C6TR01	MEDTRONIC INC.	Modification to the visual inspection of welded brackets.
P010031/S545	05/09/2016	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONCERTO II CRT- D, CONSULTA CRT-D, MAXIMO II CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the integrated circuit wafer manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S548	05/25/2016	X - 30-Day Notice	Amplia MRI CRT-D DTMB1D4; Amplia MRI Quad CRT-D DTMB1QQ; Brava CRT-D DTBC1D4; Brava CRT-D DTBC1D1; Brava Quad CRT-D DTBC1Q1; Brava Quad CRT-D DTBC1QQ; Compia MRI CRT-D DTMC1D4; Compia MRI Quad CRT-D DTMC1QQ; Viva Quad S CRT-D DTBB1Q1, DTBB1QQ; Viva Quad XT CRT-D DTBA1Q1, DTBA1QQ; Viva S CRT-D DTBB1D1, DTBB1D4; Viva XT CRT-D DTBA1D1, DTBA1D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the supplier's cleaning process for the accelerometer.
P010031/S549	05/25/2016	X - 30-Day Notice	AMPLIA MRI CRT-D; QUAD CRT-D; BRAVA CRT-D; BRAVA QUAD CRT-D; COMPIA MRI CRT-D; QUAD CRT-D; CONCERTO, CONSULTA, MAXIMO II, PROTECTA CRT-D; PROTECTA XT, VIVA QUAD S CRT-D; VIVA QUAD XT CRT-D, VIVA S CRT-D,VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the wafer manufacturing process.
P010032/S117	05/27/2016	X - 30-Day Notice	Tripole, Tripole 16C, Tripole 16, Exclaim, Lamitrode 4, Lamitrode 44, Lamitrode S-4, Lamitrode S-8, Lamitrode 88, Lamitrode winged, Lamitrode, Penta, Quattrode, Octrode, Dual 4 Extension, Single 8 Extension, A127¿ Extension, 8 Channel Adapters, Compustim Adapter	St. Jude Medical	Addition of an alternate supplier of inner tubing and addition of isopropyl alcohol to aid in the assembly of SCS and DBS leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020004/S130	05/05/2016	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Use of PTFE and PTFE/FEP fibers made by an approved supplier in the manufacture of the EXCLUDER AAA Endoprosthesis and Iliac Branch Endoprosthesis.
P020024/S045	05/04/2016	X - 30-Day Notice	AMPLATZER MULTI-FENESTRATED SEPTAL OCCULDER (CRIBRIFORM)	AGA MEDICAL CORP.	Addition of a new laser welding system.
P030005/S135	05/25/2016	X - 30-Day Notice	VALITUDE, VALITUDE X4, INVIVE, INTUA	GUIDANT CORP.	Additional leak tester to the battery manufacturing line.
P030005/S136	05/25/2016	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY- PACEMAKER (CRT-P); INVIVE AND INTUA MODELS. INGENIO 2. VALITUDE MODEL U125 ; VALITUDE X4 MODEL: V128	GUIDANT CORP.	Addition of a new acrylic dispense system in the pulse generator header manufacturing process.
P030054/S303	05/01/2016	X - 30-Day Notice	QuickFlex u and Quartet CRT leads	St. Jude Medical	Alternate analytical testing laboratory and implementation of an identity test for monolithic controlled release devices.
P040008/S013	05/31/2016	X - 30-Day Notice	VIDAS TOTAL PSA	BIOMERIEUX, INC.	Change of subcontractor of mouse ascite.
P040040/S028	05/04/2016	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORP.	Addition of a new laser welding system.
P040043/S085	05/17/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Use of PTFE fibers made by an approved supplier in the manufacture of the Conformable TAG Thoracic Endoprosthesis (CTAG Device).
P040044/S072	05/04/2016	X - 30-Day Notice	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	ACCESS CLOSURE, INC.	Modify the balloon material resin of the MynxAce balloon catheter.
P040045/S056	05/06/2016	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification to the statistical method and procedures for product sampling of finished product release.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050028/S051	05/13/2016	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new filler system and transfer of the microtube filling operations of controls to a new laboratory.
P050047/S053	05/26/2016	X - 30-Day Notice	JUVEDERM Hyaluronate Gel Implants	ALLERGAN	Authorization for the implementation of new equipment for scale-up of Juvederm manufacturing processes.
P060030/S051	05/13/2016	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new filler system and transfer of the microtube filling operations of controls to a new laboratory.
P070026/S035	05/17/2016	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of a laser marking machine to the manufacturing process.
P080025/S107	05/05/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Relocation of the parts cleaning of the impacted piece parts (components) from the Medtronic Sullivan Lake (SL) facility to the Medtronic Rice Creek (RC) facility.
P080027/S023	05/10/2016	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Relocation of the manufacturing process for an OraQuick® HCV Rapid Antibody Test component to another OraSure manufacturing facility.
P100020/S019	05/13/2016	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new filler system and transfer of the microtube filling operations of controls to a new laboratory.
P100042/S010	05/20/2016	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Addition of a new manufacturing site, scale-up, cleaning process, and automated filling for reagent production.
P100047/S074	05/19/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	New facility (same supplier) to provide the battery charger for the HeartWare Ventricular Assist System (HAVD).
P100049/S017	05/19/2016	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Process change is for gross leak hermeticity testing.
P110010/S124	05/10/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Install an additional stent wetline and inspection equipment to the (BSC) Maple Grove facility.

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P110010/S125	05/20/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the software on the automated catheter manufacturing line.
P110013/S068	05/25/2016	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Extension of the Laboratory Information Management System (LIMS) capabilities.
P110020/S015	05/13/2016	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Proposed change is to transfer tube filling device and location.
P110037/S026	05/13/2016	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new filler system and transfer of the microtube filling operations of controls to a new laboratory.
P110043/S010	05/27/2016	X - 30-Day Notice	OMNILINK ELITE VASCULAR BALLOON-EXPANDABLE STENT SYSTEM	ABBOTT VASCULAR-CARDIAC THERAPIES	Alternate sampling plan for process monitoring.
P120011/S004	05/11/2016	X - 30-Day Notice	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Replacement of dry heat sterilization temperature sensors from pyrobuttons to thermocouples and added digital temperature chart printout, located in Specialty Silicone Fabricators (SSF), 2761 Walnut Avenue, Tustin, California, 92780.
P120011/S005	05/13/2016	X - 30-Day Notice	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Manufacturing sequence change: baffle shell slitting process was moved to follow the 2-inch hole die-cutting step, instead of preceding it. The facility is located in Specialty Silicone Fabricators (SSF), 2761 Walnut Avenue, Tustin, CA 92780.
P120019/S009	05/13/2016	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Proposed change is to transfer tube filling device and location.

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P130007/S013	05/12/2016	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Change to implement a new fixture, new set-up configuration, and a control software modification for the purpose of increasing throughput for one of the incoming inspection processes used for lot acceptance of the insulin cartridges of the Animas Vibe Insulin Pump. The Animas Vibe Insulin Pump is a component of the Animas Vibe System.
P130008/S011	05/16/2016	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Transfer of cleaning process from the Medtronic Sullivan Lake, Minneapolis, MN facility (SL) to the Medtronic Rice Creek, Minneapolis, MN facility (RC).
P130008/S012	05/20/2016	X - 30-Day Notice	INSPIRE PROGRAMMER SYSTEM	INSPIRE MEDICAL SYSTEMS	Change to replace the machined housing with a new injection molded housing for the Model 2740 Inspire Programmer System (IPS) telemetry module box.
P130009/S055	05/06/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Additional bovine pericardial tissue supplier.
P130013/S007	05/05/2016	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Modifications to in-process microbiology testing.
P130017/S008	05/03/2016	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualification of facility for receiving, inspection and storage of product components.
P130017/S009	05/05/2016	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualify an alternative supplier for reagents utilized in the Cologuard assay.
P130028/S006	05/13/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	ALGOSTIM, LLC	Optional replacement of a diode hand-soldering process with an automated surface mount technology process and optional replacement of an uncoated wire with a zero Ohm resistor on the printed circuit boards for the Model 4200 patient programmer charger of your Algovita Spinal Cord Stimulation system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130030/S024	05/10/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Install an additional stent wetline and inspection equipment to the (BSC) Maple Grove facility.
P140009/S014	05/27/2016	X - 30-Day Notice	DBS Extensions	ST. JUDE MEDICAL NEUROMODULATION	Addition of an alternate supplier of inner tubing and addition of isopropyl alcohol to aid in the assembly of SCS and DBS leads.
P140017/S003	05/04/2016	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Add bovine tissue suppliers used to manufacture the valve.
P140023/S005	05/13/2016	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Proposed change is to transfer tube filling device and location.
P140028/S012	05/11/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Addition of new manufacturing equipment and an associated process.
P140028/S013	05/27/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	Boston Scientific Corporation	Updates to the manufacturing process.
P140031/S013	05/06/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Additional bovine pericardial tissue supplier.
P150003/S009	05/10/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Install an additional stent wetline and inspection equipment to the (BSC) Maple Grove facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150003/S010	05/18/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MR & OTW	Boston Scientific Corporation	Combine pre-weighing and pre-reducing equipment.
P150003/S012	05/20/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MR & OTW	Boston Scientific Corporation	Update to the software on the automated catheter manufacturing line.
P150012/S001	05/25/2016	X - 30-Day Notice	ESSENTIO VALITUDE MRI, PROPONENT VALITUDE MRI, ACCOLADE VALITUDE MRI	BOSTONSCIENTIFIC	Additional leak tester to the battery manufacturing line.
P150012/S002	05/31/2016	X - 30-Day Notice	ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI Pacemakers	BOSTONSCIENTIFIC	Implementation of the following previously accepted manufacturing changes: 1) Removal of a plating process on the crystal oscillator component; 2) modifications to the crystal oscillator manufacturing process; 3) addition of an alternate supplier of a battery raw material; 4) addition of an alternate supplier of the power conductor component; 5) addition of an alternate supplier of the telemetry coils; 6) addition of an alternate supplier of capacitors; 7) addition of an automated visual inspection system for coil springs; 8) addition of an automated packaging line; and 9) vertical integration of the spring connector housing block.
P150012/S003	05/25/2016	X - 30-Day Notice	PACEMAKER MODELS. ESSENTIO , PROPONENT, ACCOLADE MRI'S	BOSTONSCIENTIFIC	Addition of a new acrylic dispense system in the pulse generator header manufacturing process.
P150033/S001	05/25/2016	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Change to the supplier's cleaning process for the accelerometer.

Total: 107